

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

Attorney Docket Number	4239-66912-02
Application Number	10/530,254
Filing Date	April 4, 2005
First Named Inventor	Sternberg
Art Unit	1646
Examiner Name	Not Yet Assigned

## **U.S. PATENT DOCUMENTS**

Copies of U.S. Patent documents do not need to be provided, unless requested by the Patent and Trademark Office. For patents, provide the patent number and the issue date. For published U.S. applications, provide the publication number and the publication date. For unpublished pending patent applications, provide the application number and the filing date.

Examiner's Initials*	Cite No. (optional)	Number	Publication Date	Name of Applicant or Patentee
/GC/		5,846,711	12/08/1998	Moore <i>et al.</i>

## **FOREIGN PATENT DOCUMENTS**

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee

## **OTHER DOCUMENTS**

Examiner's Initials*	Cite No. (optional)	OTHER DOCUMENTS
/GC/		Written Opinion of the International Searching Authority, mailed September 28, 2005, for corresponding International Application No. PCT/US2003/0031406, 6 pages.
		European Patent Office, "Communication -European Search Report" for European Application No. EP03773114.8 - 2401, February 15, 2006, 5 pages.
		S.H. Leppla, "The Comprehensive Sourcebook of Bacterial Protein Toxins," 3 <sup>rd</sup> edition, 323-347, 2006.
↓		Webster, <i>et al.</i> , "Anthrax lethal toxin represses glucocorticoid receptor (GR) transactivation by inhibiting GR-DNA binding in vivo," <i>Mol. Cell. Endo.</i> , 241(1): 21-31, 2005.

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/GC/		5,006,330	09 Apr 1991	Sternberg <i>et al.</i>
/GC/		5,677,274	14 Oct 1997	Leppla <i>et al.</i>
/GC/		US2003/0207833 A1	06 Nov 2003	Berkley <i>et al.</i>

## **FOREIGN PATENT DOCUMENTS**

Examiner's Initials*	Cite No. (optional)	Country	Number	Publication Date	Name of Applicant or Patentee
/GC/		WIPO/PCT	WO 98/26783	25 June 1998	Hoechst Marion Roussel
↓		WIPO/PCT	WO 98/27986	02 July 1998	Zymogenetics, Inc.
↓		WIPO/PCT	WO 99/50439	07 Oct 1999	The Government of the United States of America as Represented by the Secretary, Department of Health and Human Services
↓		WIPO/PCT	WO 01/21656	29 Mar 2001	The Government of the United States of America as Represented by the Secretary, Department of Health and Human Services

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Examiner's Initials*	Cite No. (optional)	<b>OTHER DOCUMENTS</b>	
IGC/		ARORA <i>et al.</i> , "Fusions of anthrax toxin lethal factor to the ADP-ribosylation domain of Pseudomonas exotoxin A are potent cytotoxins which are translocated to the cytosol of mammalian cells," <i>The Journal of Biological Chemistry</i> 267(22):15542-15548, 1992	
		ARORA <i>et al.</i> , "Residues 1-254 of anthrax toxin lethal factor are sufficient to cause cellular uptake of fused polypeptides," <i>The Journal of Biological Chemistry</i> 268(5):3334-3341, 1993	
		ARORA <i>et al.</i> , "Fusions of anthrax toxin lethal factor with shiga toxin and diphtheria toxin enzymatic domains are toxic to mammalian cells," <i>Infection and Immunity</i> 62(11):4955-4961, 1994	
		ARORA <i>et al.</i> , "Cytotoxic effects of a chimeric protein consisting of tetanus toxin light chain and anthrax toxin lethal factor in non-neuronal cells," <i>The Journal of Biological Chemistry</i> 269(42):26165-26171, 1994	
		BHATNAGAR <i>et al.</i> , "Calcium is required for the expression of anthrax lethal toxin activity in the macrophagelike cell line J774A.1," <i>Infection and Immunity</i> 57(7):2107-2114, 1989	
		BHATNAGAR <i>et al.</i> , "Protein synthesis is required for expression of anthrax lethal toxin cytotoxicity," <i>Infection and Immunity</i> 62(7):2958-2962, 1994	
		BHATNAGAR <i>et al.</i> , "Anthrax toxin," <i>Clinical Reviews in Microbiology</i> 27(3):167-200, 2001	
		BLEDSOE <i>et al.</i> , "Crystal structure of the glucocorticoid receptor ligand binding domain reveals a novel mode of receptor dimerization and coactivator recognition," <i>Cell</i> 110:93-105, 2002	
		BRADLEY <i>et al.</i> , "Identification of the cellular receptor for anthrax toxin," <i>Nature</i> 414:225-229, 2001	
		CASTAGLIUOLO <i>et al.</i> , "Endogenous corticosteroids modulate Clostridium difficile toxin A-induced enteritis in rats," <i>Am J Physiol Gastrointest Liver Physiol</i> 280:G539-G545, 2001	
		CHAUDRY <i>et al.</i> , "Quickening the pace of anthrax research: three advances point towards possible therapies," <i>Trends in Microbiology</i> 10(2):58-62, 2002	
		DUESBERY <i>et al.</i> , "Proteolytic inactivation of MAP-kinase-kinase by anthrax lethal factor," <i>Science</i> 280:734-737, 1998	
↓		DUESBERY <i>et al.</i> , "Anthrax lethal factor causes proteolytic inactivation of mitogen-activated protein kinase kinase," <i>Journal of Applied Microbiology</i> 87:289-293, 1999	

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/GCI/		DUESBERY <i>et al.</i> , "Suppression of ras-mediated transformation and inhibition of tumor growth and angiogenesis by anthrax lethal factor, a proteolytic inhibitor of multiple MEK pathways," <i>Proc. Natl. Acad. Sci. USA</i> 98(7):4089-4094, 2001	
		EDWARDS <i>et al.</i> , "The pituitary gland is required for protection against lethal effects of <i>Salmonella typhimurium</i> ," <i>Proc. Natl. Acad. Sci. USA</i> 88:2274-2277, 1991	
		ERWIN <i>et al.</i> , "Macrophage-derived cell lines do not express proinflammatory cytokines after exposure to <i>Bacillus anthracis</i> lethal toxin," <i>Infection and Immunity</i> 69(2):1175-1177, 2001	
		EZZELL <i>et al.</i> , "Immunoelectrophoretic analysis, toxicity, and kinetics of in vitro production of the protective antigen and lethal factor components of <i>Bacillus anthracis</i> toxin," <i>Infection and Immunity</i> 45(3):761-767, 1984	
		FRIEDLANDER, "Protein kinase C activation has dissimilar effects on sodium-coupled uptakes in renal proximal tubular cells in primary culture," <i>The Journal of Biological Chemistry</i> 261(16):7123-7126, 1986	
		FRIEDLANDER <i>et al.</i> , "Characterization of macrophage sensitivity and resistance to anthrax lethal toxin," <i>Infection and Immunity</i> 61(1):245-252, 1993	
		GLASS <i>et al.</i> , "Nuclear receptor coactivators," <i>Current Opinion in Cell Biology</i> 9:222-232, 1997	
		GODOWSKI <i>et al.</i> , "Glucocorticoid receptor mutants that are constitutive activators of transcriptional enhancement," <i>Nature</i> 325(6102):365-368, 1987 (Abstract)	
		GOMEZ <i>et al.</i> , "Endogenous glucocorticoids attenuate Shiga toxin-2-induced toxicity in a mouse model of haemolytic uraemic syndrome," <i>Clin Exp Immunol</i> 131:217-224, 2003	
		HAMMOND <i>et al.</i> , "Lethal factor active-site mutations affect catalytic activity in vitro," <i>Infection and Immunity</i> 66(5):2374-2378, 1998	
		HANNA <i>et al.</i> , "Role of macrophage oxidative burst in the action of anthrax lethal toxin," <i>Molecular Medicine</i> 1(1):7-18, 1994	
		HANNA <i>et al.</i> , "Understanding <i>Bacillus anthracis</i> pathogenesis," <i>Trends in Microbiology</i> 7(5):180-182, 1999	
		HANNA, "Lethal toxin actions and their consequences," <i>Journal of Applied Microbiology</i> 87:285-287, 1999	
		HERRLICH, "Cross-talk between glucocorticoid receptor and AP-1," <i>Oncogene</i> 20:2465-2475, 2001	
↓		KARIN <i>et al.</i> , "AP-1--glucocorticoid receptor crosstalk taken to a higher level," <i>Journal of Endocrinology</i> 169:447-451, 2001	

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/GC/		KLEIN <i>et al.</i> , "Dual Nature of Resistance Mechanisms as Revealed by Studies of Anthrax Septicemia," <i>J. Bacteriol.</i> 85:1032-1038, 1963	
		KLIMPEL <i>et al.</i> , "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci. USA</i> 89:10277-10281, 1992	
		KLIMPEL <i>et al.</i> , "Anthrax toxin lethal factor contains a zinc metalloprotease consensus sequence which is required for lethal toxin activity," <i>Molecular Microbiology</i> 13(6):1093-1100, 1994	
		KOO <i>et al.</i> , "Apoptosis and melanogenesis in human melanoma cells induced by anthrax lethal factor inactivation of mitogen-activated protein kinase kinase," <i>PNAS</i> 99(5):3052-3057, 2002	
		KRSTIC <i>et al.</i> , "Mitogen-activated and cyclin-dependent protein kinases selectively and differentially modulate," <i>Molecular and Cellular Biology</i> 17(7):3947-3954, 1997	
		LEPPLA, "Production and purification of anthrax toxin," <i>Methods in Enzymology</i> 165:103-116, 1 <sup>st</sup> ed., Academic Press, 1998	
		LEPPLA, "Anthrax Toxin," <i>Handbook of Experimental Pharmacology</i> , Vol. 145, Chapter 19, pp. 445-472, 2000	
		LITTLE <i>et al.</i> , "Production and characterization of monoclonal antibodies against the lethal factor component of Bacillus anthracis lethal toxin," <i>Infection and Immunity</i> 58(6):1606-1613, 1990	
		LITTLE <i>et al.</i> , "Characterization of lethal factor binding and cell receptor binding domains of protective antigen of Bacillus anthracis using monoclonal antibodies," <i>Microbiology</i> 142:707-715, 1996	
		LOPEZ <i>et al.</i> , "Growth factors signal to steroid receptors through mitogen-activated protein kinase regulation of p160 coactivator activity," <i>The Journal of Biological Chemistry</i> 276(25):22177-22182, 2001	
		LUCIBELLO <i>et al.</i> , "Mutual transrepression of Fos and the glucocorticoid receptor: involvement of a functional domain in Fos which is absent in FosB," <i>The EMBO Journal</i> 9(9):2827-2834, 1990	
		KAU <i>et al.</i> , "Calyculin A sensitive protein phosphatase is required for Bacillus anthracis lethal toxin induced cytotoxicity," <i>Current Microbiology</i> 44:106-111, 2002	
		MACPHEE <i>et al.</i> , "Spontaneous recovery of rats from experimental allergic encephalomyelitis is dependent on regulation of the immune system by endogenous adrenal corticosteroids," <i>J. Exp. Med.</i> 169:431-445, 1989	

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/GC/		MCEWAN <i>et al.</i> , "Interaction of the human androgen receptor transactivation function with the general transcription factor TFIIF," <i>Proc. Natl. Acad. Sci. USA</i> 94:8485-8490, 1997	
		MCKENNA <i>et al.</i> , "Minireview: nuclear receptor coactivators--an update," <i>Endocrinology</i> 143(7):2461-2465, 2002	
		MIESFELD <i>et al.</i> , "Genetic complementation of a glucocorticoid receptor deficiency by expression of cloned receptor cDNA," <i>Cell</i> 46(3):389-399, 1986 (Abstract)	
		MIESFELD <i>et al.</i> , "Glucocorticoid receptor mutants that define a small region sufficient for enhancer activation," <i>Science</i> 236(4800):423-427, 1987 (Abstract)	
		NEECK <i>et al.</i> , "Neuroendocrine perturbations in fibromyalgia and chronic fatigue syndrome," <i>Neuroendocrine Mechanisms in Rheumatic Disease</i> 26(4):989-1002, 2000	
		PANNIFER <i>et al.</i> , "Crystal structure of the anthrax lethal factor," <i>Nature</i> 414:229-233, 2001	
		PELLIZZARI <i>et al.</i> , "Anthrax lethal factor cleaves MKK3 in macrophages and inhibits the LPS/IFNgamma-induced release of NO and TNFalpha," <i>FEBS Letters</i> 462:199-204, 1999	
		PELLIZZARI <i>et al.</i> , "Lethal factor of Bacillus anthracis cleaves the N-terminus of MAPKKs: analysis of the intracellular consequences in macrophages," <i>Int. J. Med. Microbiol.</i> 290:421-427, 2000	
		PEZARD <i>et al.</i> , "Contribution of individual toxin components to virulence of Bacillus anthracis," <i>Infection and Immunity</i> 59(10):3472-3477, 1991	
		PRICE <i>et al.</i> , "Protection against anthrax lethal toxin challenge by genetic immunization with a plasmid encoding the lethal factor protein," <i>Infection and Immunity</i> 69(7):4509-4515, 2001	
		QUINN <i>et al.</i> , "Functional mapping of anthrax toxin lethal factor by in-frame insertion mutagenesis," <i>The Journal of Biological Chemistry</i> 266(30):20124-20130, 1991	
		REICHARDT <i>et al.</i> , "Mice with an increased glucocorticoid receptor gene dosage show enhanced resistance to stress and endotoxic shock," <i>Molecular and Cellular Biology</i> 20(23):9009-9017, 2000	
		ROBERTS <i>et al.</i> , "Ltx1, a mouse locus that influences the susceptibility of macrophages to cytolysis caused by intoxication with Bacillus anthracis lethal factor, maps to chromosome 11," <i>Molecular Microbiology</i> 29(2):581-591, 1998	
↓		ROBERTSON <i>et al.</i> , "Molecular cloning and expression in Escherichia coli of the lethal factor gene of Bacillus anthracis," <i>Gene</i> 44:71-78, 1986	

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/GC/		ROGATSKY <i>et al.</i> , "Antagonism of glucocorticoid receptor transcriptional activation by the c-Jun N-terminal kinase," <i>Proc. Natl. Acad. Sci. USA</i> 95(5):2050-2055, 1998
		RUZEK <i>et al.</i> , "Endogenous glucocorticoids protect against cytokine-mediated lethality during viral infection," <i>The Journal of Immunology</i> 162:3527-3533, 1999
		SCHMITT <i>et al.</i> , "Bacterial toxins: friends or foes?" <i>Emerging Infectious Diseases</i> 5(2):224-234, 1999
		SCHÜLE <i>et al.</i> , "Functional antagonism between oncoprotein c-Jun and the glucocorticoid receptor," <i>Cell</i> 62:1217-1226, 1990
		SHANKS <i>et al.</i> , "Mouse strain differences in plasma corticosterone following uncontrollable footshock," <i>Pharmacology Biochemistry &amp; Behavior</i> 36:515-519, 1990
		SHIN <i>et al.</i> , "Intracellular calcium antagonist protects cultured peritoneal macrophages against anthrax lethal toxin-induced cytotoxicity," <i>Cell Biology and Toxicology</i> 16:137-144, 2000
		SINGH <i>et al.</i> , "Internalization and processing of Bacillus anthracis lethal toxin by toxin-sensitive and -resistant cells," <i>The Journal of Biological Chemistry</i> 264(19):11099-11102, 1989
		SINGH <i>et al.</i> , "Oligomerization of anthrax toxin protective antigen and binding of lethal factor during endocytic uptake into mammalian cells," <i>Infection and Immunity</i> 67(4):1853-1859, 1999
		STERNBERG <i>et al.</i> , "Inflammatory mediator-induced hypothalamic-pituitary-adrenal axis activation is defective in streptococcal cell wall arthritis-susceptible Lewis rats," <i>Proc. Natl. Acad. Sci. USA</i> 86:2374-2378, 1989
		TANG <i>et al.</i> , "Proteasome activity is required for anthrax lethal toxin to kill macrophages," <i>Infection and Immunity</i> 67(6):3055-3060, 1999
		VITALE <i>et al.</i> , "Susceptibility of mitogen-activated protein kinase kinase family members to proteolysis by anthrax lethal factor," <i>Biochem. J.</i> 352:739-745, 2000
		WADE <i>et al.</i> , "Anthrax toxin components stimulate chemotaxis of human polymorphonuclear neutrophils," <i>Proceedings of the Society for Experimental Biology and Medicine</i> , 179:159-162, 1985
		WATTERS <i>et al.</i> , "Kif1C, a kinesin-like motor protein, mediates mouse macrophage resistance to anthrax lethal factor," <i>Current Biology</i> 11:1503-1511, 2001
		WEBSTER <i>et al.</i> , "Neuroendocrine regulation of immunity," <i>Annu. Rev. Immunol.</i> 20:125-163, 2002
↓		WEBSTER <i>et al.</i> , "Anthrax lethal factor represses glucocorticoid and progesterone receptor activity," <i>PNAS</i> 100(10):5706-5711, 2003

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/GC/		WELKOS <i>et al.</i> , "Differences in susceptibility of inbred mice to <i>Bacillus anthracis</i> ," <i>Infection and Immunity</i> 51(3):795-800, 1986	
/GC/		ZUCKERMAN <i>et al.</i> , "In vivo inhibition of lipopolysaccharide-induced lethality and tumor necrosis factor synthesis by <i>Rhodobacter sphaeroides</i> diphosphoryl lipid A is dependent on corticosterone induction," <i>Infection and Immunity</i> 60(7):2581-2587, 1992	

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